DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF MOMETASONE FUROATE AND TERBINAFINE HYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM

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Abstract

Absorption correction spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Mometasone furoate and Terbinafine hydrochloride in pharmaceutical dosage form. Accurate and precised UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of MF and TH. The method employed Absorption correction spectroscopy method based on the measurement of absorbance of MF at 250 nm and TH at 282 nm. The calibration curve was linear in a concentration range of 1-6µg/ml for MF and 10-60µg/ml for TH. The RP-HPLC method has shown adequate separation of MF and TH in pharmaceutical dosage form. The separation was achieved on a Enable C18 (250 mm - 4.6 mm, 5 µm particle size) with an isocratic system of Methanol:Water in the ratio of 95:5 v/v. The mobile phase at a flow rate of 1.5 ml/min, Injection volume 20µl and wavelength of detection used was 270 nm. The retention time for MF and TH was obtained as 2.374 min and 5.296 min respectively. The linearity of the proposed method was investigated in the range of 1-6µg/ml and 10-60µg/ml for MF and TH respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, robustness and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of MF and TH In Marketed dosage Form.

Key words: Mometasone furoate, Terbinafine hydrochloride, Absorption correction spectroscopy, RP-HPLC, Validation.